Serial No.: 10/764,222 Docket No.: 506401-0059

## **REMARKS**

Claims 1-19 are pending in this application. Claims 2-12 have been amended to clarify the invention but not for reasons of patentability.

## I. Objection to the Claims

Claim 2 was objected to under 37 C.F.R. § 1.75(c) as being in improper dependent form for failing to further limit the subject matter of the composition recited in claim 1. Claim 2 has been amended in order to clarify the limitation that is being added. Claim 2 has been amended to state that the composition is aversive to a person when ingested or inhaled. Such a limitation imparts a material limitation to the composition of claim 1. It limits the composition to those compositions aversive to a person. A composition that contains an agent that is aversive to a dog but desirable to a person is covered by claim 1, assuming the other limitations of the claim are met, but would not be covered claim 2. For the foregoing reasons, the objection to claim 2 should be removed.

## II. §112 Rejection

Claims 8-12 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The term "about" in claims 8, 9, and 11 has been deleted. Claims 10 and 12 depend from these claims and accordingly no longer incorporate this expression. In view of the amendments to these claims, Applicant submits that claims 8-12 are definite and the § 112 rejection should be withdrawn.

## III. §103 Rejection

Applicant submits that claims 1-19 are not obvious over U.S. Patent No. 5,290,775 to Sawyer et al. (Sawyer '775) in view of U.S. Patent No. 5,720,951 to Baker (Baker), U.S. Patent Application Publication No. 2003/0064099 to Oshlack et al. (Oshlack), U.S. Patent No.

Serial No.: 10/764,222 Docket No.: 506401-0059

4,005,038 to Minkoff (Minkoff), U.S. Patent No. 5,962,963 to Komer (Komer), and U.S. Patent No. 5,281,611 to Sawyer et al. (Sawyer '611).

# No Prima Facie Case of Obviousness Has Been Established

As the standard for assessing obviousness, MPEP 706.02(j) lists three requirements for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103:

- (1) First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the references to arrive at the claimed invention.
- (2) Second, there must be a reasonable expectation of success.
- (3) Finally, the prior art references must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure.

It is respectfully submitted that these three requirements have not been met. Therefore, Applicant respectfully submits that a *prima facie* case of obviousness for rejecting the pending claims has not been established. Claims 1-19 are not anticipated or made obvious by Sawyer '775 in view of Baker, Oshlack, Minkoff, Komer and Sawyer '611.

Sawyer '775, Komer, and Sawyer '611 do not disclose or suggest an injectable euthanasia formulation containing a taste aversive agent, as claimed by Applicant in all of the pending claims. Baker, Oshlack and Minkoff are cited for disclosing compositions that contain a taste aversive substance. However, none of the compositions disclosed by Baker, Oshlack or Minkoff is a euthanasia solution, as claimed by Applicant in claims 1-19.

There is no suggestion or motivation from the cited references to incorporate the taste aversive substance from Baker, Oshlack, or Minkoff into the euthanasia solution of Sawyer '775, Komer, or Sawyer '611. More specifically, there is no suggestion or motivation from the cited

Serial No.: 10/764,222

Docket No.: 506401-0059

references that a taste aversive agent would be chemically compatible with the chemicals in an injectable euthanasia solution. Oshlack's teachings of adding a taste aversive agent to an opioid analgesic does not imply or suggest that a taste aversive agent could be added to a euthanasia composition.

With no teaching or suggestion from the cited references to incorporate a taste aversive agent into an injectable euthanasia composition, one of ordinary skill in the art would not find such an addition to be obvious in view of the fact that numerous chemicals are not compatible with euthanasia formulations. For instance, as taught by Sawyer '775 in column 19, lines 40-50, using isopropyl alcohol in a euthanasia formulation provided undesirable effects. Accordingly, there is no reasonable expectation from the cited references or the knowledge of a person of ordinary skill in the art that a taste aversive agent could be successfully incorporated into a euthanasia formulation.

It is important to delicately balance the chemicals in a euthanasia formulation so as not to cause an inhumane death, such as a prolonged death or unwanted side effects during the euthanizing process. Accordingly, one of ordinary skill in the art would not assume that a taste aversive agent could be added to a euthanasia formulation to create an injectable euthanasia composition.

With respect to claims 8-12, there is no suggestion or motivation that a taste aversive agent would be chemically compatible with an injectable euthanasia composition containing a cardiotoxic compound, such a quinacrine compound, a chloroquine compound or salts thereof, and containing gamma-hydroxy butramide.

Still further, there is no suggestion or motivation that a taste aversive agent would be chemically compatible when using an anesthetic such as propofol, as claimed in claim 16.

Serial No.: 10/764,222

Docket No.: 506401-0059

Komer, which discloses a propofol formulation, does not disclose or suggest incorporating a taste aversive agent.

In addition, neither Baker, Minkoff, nor Oshlack provide motivation to incorporate a taste aversive agent into a formulation intended for injection, as claimed by Applicant. Baker incorporates a taste aversive agent into a rodenticide bait that is orally consumed in a solid form. Minkoff incorporates a taste aversive agent in a coating composition for covering paint. Oshlack incorporates a taste aversive agent into an opioid analgesic that is consumed orally. Neither Baker, Minkoff, nor Oshlack intend his invented composition to be injectable.

Still further, Oshlack teaches away from the injectable composition of the present invention by teaching at paragraph 41 a composition that is "preferably for use in connection with oral dosage forms including opioid analgesics." Oshlack tries to prevent injection of his formulation so as to prevent abuse of the opioid analgesics. In fact, Oshlack's only mention of injection involves trying to prevent it. Accordingly, the cited references do not teach or suggest incorporating a taste aversive agent into a composition that is administered by injection. Thus, there is no suggestion by the cited references of an injectable euthanasia composition that includes a taste aversive agent, as claimed by Applicant.

For the foregoing reasons, Applicant submits that claims 1-19 are not anticipated or made obvious by Sawyer '775 in view of Baker, Oshlack, Minkoff, Komer and Sawyer '611.

### III. **Conclusion**

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments that need be addressed in order to obtain allowance, please contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Serial No.: 10/764,222 Docket No.: 506401-0059

Respectfully submitted,

Susan Wharton Bell, Reg. No. 41,524

STINSON MORRISON HECKER LLP

1201 Walnut Street, Suite 2800

Kansas City, MO 64106-2150

Telephone: (816) 842-8600

Facsimile: (816) 691-3495